United States District Court
Northern District of California

**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

**SAN JOSE DIVISION**

MARY JANE JASIN, et al.,

Plaintiffs,

v.

VIVUS, INC., et al.,

Defendants.

Case No. 14-cv-03263-BLF

**ORDER GRANTING MOTION TO DISMISS AND DENYING MOTION FOR ENTRY OF PARTIAL JUDGMENT**

[Re: ECF 35, 38]

Plaintiffs, two individual investors, lost more than $2.8 million through their investment in Defendant Vivus, Inc., a pharmaceutical company that sought approval for its obesity drug in the United States and Europe but was approved only in the United States. Plaintiffs allege that their losses were caused by Defendants' failure to accurately disclose concerns raised during the European regulatory review, which inflated share prices, and to disclose the specific timing of Vivus' planned public offering, which diluted the value. The Court previously dismissed similar allegations, but Plaintiffs now offer a fuller regulatory record and amended claims. Defendants again move to dismiss, arguing that these changes have not cured Plaintiffs' failure to adequately plead falsity, much less scienter. For the reasons stated below, the Court GRANTS the Motion to Dismiss without leave to amend.[1]

## I. BACKGROUND

Plaintiffs, a husband and wife, invested—and lost—more than $2.8 million in Defendant Vivus, Inc.'s stock. SAC ¶ 23, ECF 32. Vivus is a biopharmaceutical company that had developed an obesity drug comprised of topiramate ("TPM") and phentermine ("PHEN"). *Id.* ¶ 88. Vivus

[1] Plaintiffs' Motion for Entry of Partial Judgment under Rule 54(b), *see* ECF 35, is therefore DENIED as moot.

sought regulatory approval for the drug in the United States and the European Union. *Id.* ¶¶ 37, 44. The drug was called "Qnexa" during the U.S. process and "Qsiva" during the EU process. *Id.* ¶ 4. Ultimately, the FDA approved the drug—at which point it was renamed to "Qsymia"—while the EU's regulatory agency, European Medicines Agency ("EMA"), rejected it.[2]

During the period relevant to this suit, Defendants Leland F. Wilson, Peter Y. Tam, and Timothy Morris were Vivus' Chief Executive Officer, President and Director, and Chief Financial Officer and Senior Vice President of Finance and Global Corporate Development, respectively (collectively, "Individual Defendants"). *Id.* ¶¶ 25-27.

Plaintiffs allege that Defendants misrepresented or omitted material facts regarding (1) the EMA's review of Qsiva, including its alleged requirement that Vivus conduct a pre-approval cardiovascular ("CV") safety study and other allegedly material safety concerns, and (2) the timing of Vivus' February 28, 2012 public offering, which followed large sales of shares by the Individual Defendants and other Vivus executives. Plaintiffs allege that those misrepresentations and omissions—made in public statements, on investor calls, and in direct communications between Mr. Morris and Mr. Jasin—caused Plaintiffs to buy Vivus shares at inflated prices.

Before detailing the relevant chronology, the Court summarizes the EMA's approval process, which proves central to understanding the facts of this case. Plaintiffs describe the EU's regulatory process as follows. The EMA's Committee for Medicinal Products for Human Use ("CHMP") is responsible for evaluating Marketing Authorization Applications ("MAA") for new drugs for human use. *Id.* ¶ 45. The CHMP is comprised of individuals, including a "Rapporteur" and a "Co-Rapporteur," who are voting members and "carry a strong voice in leading the voting process." *Id.* The Rapporteur, Co-Rapporteur, and CHMP issue formal questions and comments to the applicant in prescribed formats at established intervals, typically 80, 120, and 180 days after receipt of the MAA (excluding the time the applicant takes to respond). *See id.* ¶¶ 49, 51, 53-54, 92, 107, Exhs. C, F-H, P; *see also Sec. & Exch. Comm'n v. Sabrdaran*, No. 14-CV-04825-JSC,

[2] The Second Amended Complaint interchangeably refers to the drug as "Qnexa," "Qsymia," and "Qsiva." SAC ¶ 4. For clarity, the Court uses "Qsymia" when referring to the drug approved in the U.S. and "Qsiva" when referring to the approval process in Europe.

2015 WL 901352, at *1-2 (N.D. Cal. Mar. 2, 2015). This process culminates in a CHMP vote on whether to recommend that the EMA approve or reject the drug for sale in the EU. SAC ¶ 45.

In Qsiva's case, the rapporteurs and/or CHMP issued reports at the 80, 120, and 180 day marks. *Id.* ¶¶ 49, 51, 53-54, 107. On October 18, 2012, the CHMP rejected Qsiva's application; the CHMP affirmed the rejection on February 21, 2013. Over the same time period, Vivus filed at least one Form 8-K, four Form 10-Qs, and one Form 10-K; conducted a quarterly earnings call; spoke at public conferences; gave two interviews on CNBC; and issued a press release. In addition, Mr. Morris spoke privately with Mr. Jasin over the phone and via email. Plaintiffs allege that, in those public and private communications, Defendants misrepresented or omitted material concerns the CHMP had communicated to them, as well as their plans for a public offering on February 28, 2012. The Court details the chronology below.

**A. 80 Day Reports and Related Statements**

***1. Form 8-K (April 2011)***

Vivus submitted its MAA to the EMA on December 17, 2010. *Id.* ¶ 44. On April 4, 2011, prior to any communications from the CHMP, Vivus filed its Form 8-K with the SEC. *Id.* ¶ 47. Plaintiffs challenge Vivus for failing to list cardiovascular concerns in this SEC filing. *Id.* ¶ 48.

***2. 80 Day Reports (April 2011)***

Four days later, on April 8, 2011, two 80-day responses were issued concerning Qsiva: the "Co-Rapporteurs' Day 80 Critical Assessment Report" ("Co-Rapporteur's 80 Day Report") and the "Rapporteurs' Day 80 Critical Assessment Report" ("Rapporteur's 80-Day Report"). *Id.* Exhs. F and P, ECF 32-2 and 32-8. The Co-Rapporteur's report was sent to all CHMP members and Vivus on April 11, 2011, and the Rapporteur's report was also issued to Vivus. *Id.* ¶¶ 49, 107.

In his 80 Day Report, the Co-Rapporteur concluded that, at that point, the available data showed a negative benefit-risk balance for Qsiva. *Id.* Exh. F at 62, ECF 32-2. Specifically, "cardiovascular events and . . . psychiatric disorders, cognitive impairment and potential metabolic acidosis are of concern and preclude obtaining any marketing authorisation with the available overall data." *Id.* Aware of concerns regarding the long-term health effects of Qsiva, Vivus had offered "to perform a long-term, post-approval outcomes study on long-term risks and benefits of

PHEN/TPM," but the Co-Rapporteur found that proposal unacceptable. *Id.* Instead, the report stated, "a new pharmaco-epidemiological morbidity-mortality long-term study exploring these overall issues is mandatory before any decision on marketing authorisation . . . is taken." *Id.*

With regard to CV risks, the report stated, "[T]he Co-Rapporteur considers that an international large scale simple trial, randomised versus placebo should be required **pre-approval** to demonstrate the absence of any long term deleterious effect on cardiovascular events and mortality." *Id.* at 69-70 (emphasis in original); SAC ¶ 49. Similarly, the report stated that "[t]he applicant should provide" a complete analysis of the psychiatric effects of the drug, assessed by sub-groups with and without histories of psychiatric disorders. *Id.* ¶¶ 110-112, Exh. F at 70. On the basis of these statements, Plaintiffs allege that "a completed cardio study was specified in the 'Day 80' report as a **requirement** before granting approval." *Id.* ¶ 50 (emphasis in original).

The second report issued that day, the Rapporteur's 80-Day Report, listed cognitive and psychiatric disorders as "Important identified risks," but increased heart rate as only an "Important potential risk." *Id.* ¶¶ 107-108, Exh. P at 153, 155. Like the Co-Rapporteur, the Rapporteur listed additional studies and monitoring as "planned actions." *Id.* ¶ 109, Exh. P at 156. These included "[r]outine pharmacovigilance via spontaneous ADR reporting," "[s]afety data monitoring via the [Qsiva] EU Patient Registry," and "US Outcomes trial (metabolic acidosis)." *Id.* Exh. P at 156.

The Rapporteur also raised off-label use as a "serious concern." *Id.* ¶ 115, Exh. P at 155. At the same time, his report stated that "the need for controlled drug prescribing is likely to mitigate this potential." *Id.* ¶ 116, Exh. P at 155. As a next step for this concern, the report states that "[t]he Applicant will discuss the need for risk minimisation activities, or justify why they should not be needed." *Id.* ¶ 117, Exh. P at 162.

### ***3. Form 10-Q (May 2011)***

On May 6, 2011, a month after the 80-day reports, Vivus filed its Form 10-Q. *Id.* ¶ 50. In the 10-Q, Vivus disclosed that the EMA "may request additional studies including cardiovascular outcome studies prior to granting approval" in the EU. *Id.* Vivus further explained:

> Cardiovascular outcome studies can take several years, cost millions of dollars and may result in showing an increased risk for major adverse cardiovascular

> events for patients undergoing drug treatment. If any regulatory agency were to require additional studies, including studies to address cardiovascular events, the impact on the timing of approval and, if approved, commercialization of QNEXA . . . could be delayed or adversely impacted. . . . As a result, we cannot predict when or whether regulatory approval will be obtained for any of our investigational drug candidates currently under development."

*Id.* ¶ 50. *See also* Defs' RJN Exh. 1 at 48, ECF 39-1.[3] In the same 10-Q, Vivus warned investors that even if the FDA approved the obesity drugs, regulators in other jurisdictions might not. *Id*. at 61. Vivus also noted that, if regulators required additional clinical studies, the company's future capital requirements could be significantly altered. *Id*. at 75.

**B. 120 Day Report and Related Statements**

***1. 120 Day Report (May 2011)***

Thirteen days later, on May 19, 2011, the CHMP issued the "CHMP Day 120 List of Questions – Final" ("120 Day Report"). The "Conclusions on clinical safety" identified "the main focus of serious concern" as "the increased risk of depressions as well as the known teratogenicity [capability of producing birth defects] associated with topiramate." SAC Exh. C at 51, ECF 32-1.

With regard to CV risks, the CHMP observed that Qsiva "does not seem to be associated with a detrimental effect on other cardiovascular risk factors, but instead limited beneficial effects most likely secondary to weight loss." *Id*. at 59. At the same time, the CHMP was concerned about outcomes for patients who were already at high risk for CV problems. *Id.* Thus, the CHMP found that a "CV safety in the full target population needs to be further discussed," noted that "[t]here is no withdrawal study available which is a deficiency when deciding on optimal duration of the treatment," and stated "the CV safety of PHEN/TPM should be further evaluated before approval." SAC ¶ 52(a)-(c), Exh. C at 51, 56, 59.

The Report concluded that "the beneficial effects of PHEN/TPM are of high clinical relevance," but "are currently outweighed by the uncertainties concerning how the increased risk

[3] Defendants request that the Court take judicial notice of seven documents, each of which is a copy of a document filed with the SEC. *See* RJN, ECF 39. Plaintiffs do not oppose. See Opp. at 1 n.1. These documents are appropriate for judicial notice, *see, e.g., Metzler Inv. GmbH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008). The Court GRANTS Defendants' request.

of depression, the cardiovascular safety, metabolic acidosis as well as the teratogenic potential of topimerate can be handled in clinical practice." *Id.* ¶ 52(d), Exh. C at 60. "[F]or a positive benefit/risk balance, the Applicant needs to convince the CHMP of the safe use of PHEN/TPM in clinical practice including the performance of a CV safety study including an adequate proportion of high risk patients before approval." *Id.* ¶ 52(e)-(f), Exh. C at 61.

Plaintiffs allege that the 120 Day Report made Vivus aware that a pre-approval cardiovascular study was necessary to convince the CHMP of the safety of Qsiva, and was required before it would approve market authorization. *Id.* ¶¶ 7-8, 39, 52.

***2. Form 10-Q (August 2011)***

Vivus filed a Form 10-Q in August 2011. Defs.' RJN Exh. 2, ECF 39-2. In the form, Vivus disclosed the CHMP's 120 Day Report as follows:

> We are currently reviewing the 120-day questions which cover a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited longterm safety data in high-risk patients; and known and suspected affects [*sic*] of topiramate which include CNS and teratogenic potential. The CHMP also had questions concerning our proposed risk management plan for QNEXA. The 120-day questions are consistent with the issues previously raised in the FDA review process. We are in the process of preparing our response. We will meet with representatives from the CHMP to seek clarification on certain questions and we anticipate submitting a response in the fourth quarter of 2011. We expect the CHMP to issue the 180-day opinion in the first quarter of 2012. There can be no assurance that our response will be adequate or that our MAA will be approved by the EMA.

*Id.* at 18.

The August 2011 Form 10-Q additionally disclosed, "To date, the FDA has not requested that we perform any . . . cardiovascular outcome studies pre-approval . . . The [EMA] may request . . . cardiovascular outcome studies prior to granting approval of QNEXA in the EU." The 10-Q then went on to list the same costs and risks of such a study that Vivus had identified in the May 2011 filing, concluding, "we cannot predict when or whether regulatory approval will be obtained for any of our investigational drug candidates currently under development." *Id.* at 51.

***3. Clarification Meeting (September 2011)***

Plaintiffs additionally allege that, following the 120 Day List, Vivus and the CHMP held a



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clarification meeting on September 2, 2011. At that meeting, Rapporteur K. Dunder and Co-Rapporteur Philippe Lechat allegedly asked Vivus to conduct a pre-approval cardiovascular study. Mr. Jasin learned of this meeting during a 2013 call with Mr. Lechat. SAC ¶ 56. It is unclear who from Vivus attended the meeting. Plaintiffs contend that this meeting also made the CV study a clear pre-approval requirement.

On November 3, 2011, Vivus issued a press release noting that the FDA had accepted the Company's New Drug Application ("NDA") for Qsymia. *Id.* ¶ 37.

***4. Third Quarter Earnings Call (November 2011)***

On November 7, 2011, Vivus held its Third Quarter Earnings conference call. *Id.* ¶¶ 57-58. On the call, Mr. Wilson described the September meeting as "a productive clarification meeting with our Rapporteur and Co-rapporteur in September." He then described the timeline for the next CHMP steps—Vivus' response to the 120-day questions and the CHMP's issuance of its "180-day opinion." *Id.* ¶ 58, Exh. I at 3, ECF 32-6.

During the question and answer portion, Mr. Tam responded to a question about some of the 120-day questions as follows: "The 120-day questions . . . are essentially very much consistent with some of the questions raised by the FDA as well as the Advisory Committee meeting." *Id.* ¶ 62, Exh. I at 11. In response to the next question—regarding any discussions with the FDA on a pre- or post-approval CV outcomes study—Mr. Tam stated, "one thing we have said, and remains true, is that in all of our discussion with the FDA, we've never talked about a pre-approval cardiovascular safety study." *Id.* ¶ 60, Exh. I at 11.[4] Plaintiffs allege that, in combination, these statements misrepresent the fact that the CHMP had requested a pre-approval CV study.

***5. Form 10-Q (November 2011)***

The next day, November 8, 2011, Vivus filed a 10-Q again stating that "[t]he 120-day questions are consistent with issues previously raised in the FDA review process," *id.* ¶ 63, and that "[w]e met with representatives from the CHMP in September 2011 to seek clarification on certain questions," SAC Exh. J at 18, ECF 32-7. Again, Vivus cautioned, "There can be no

[4] Plaintiffs allege that Mr. Wilson made this statement, but the transcript identifies the speaker as Mr. Tam.

assurance that our response will be adequate or that our MAA will be approved by the EMA." *Id.*

**C. 180 Day Reports, FDA Recommendation, and Fast Money Show**

***1. 180 Day Reports (December 2011/January 2012)***

The CHMP issued the "Rapporteur and co-rapporteur day 180 joint response assessment report" ("Rapporteurs' 180 Day Joint Report") on December 30, 2011. *Id.* ¶ 53, Exh. G, ECF 32-3. The report again found that the overall benefits/risk ratio of Qsiva was negative. *Id.* ¶ 53(c), Exh. G at 66. Specifically, "[t]he lack of a CV safety study as well as the proposed risk minimisation activities with respect to psychiatric adverse events and pregnancy prevention . . . needs to be further justified." *Id.* ¶ 53(b), Exh. G at 66. In addition, "Long term data in the context of the aim to prevent cardiovascular events is limited. There is no withdrawal study available which is a deficiency when deciding an optimal duration of the treatment." *Id.* ¶ 53(a), Exh. G at 62.

The CHMP also issued its own "Day 180 List of Outstanding Issues" ("CHMP 180 Day Report"). *Id.* ¶ 54. The CHMP 180 Day Report also found the "benefit/risk balance of all dosages in the target population . . . negative . . . The overall benefit/risk balance needs to be further justified." *Id.* ¶¶ 53(c), 54(c), Exh. H at 61, ECF 32-5. Specifically, "the applicant should further justify the lack of deleterious cardiovascular effects in both low and high risk populations as well as the lack of cardiovascular safety study before approval." *Id.* ¶¶ 53(b), 54(d), Exh. H at 61. In addition, the absence of heart rate results in a high-risk population from "a study before approval needs further justification." *Id.* ¶ 55, Exh. H at 52. The 180 Day List also identified cognitive and psychiatric disorders as areas of concern. *Id.* ¶¶ 113, 118. Exh. H at 52.[5]

***2. FDA Recommendation and Fast Money Halftime Show (February 2012)***

In the week preceding February 27, 2012, an FDA panel recommended full approval of Qsymia for sale in the United States. *Id.* ¶ 123. Vivus shares increased by more than 125 percent over the following week. *Id.* ¶ 123. During the same week, Mr. Wilson and Mr. Morris exercised their options and sold 429,358 shares of Vivus stock. *Id.* ¶ 131.

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[5] Plaintiff additionally alleges that the 180 Day Report states that Vivus "should discuss the need for risk minimization activities, or justify why they should not be needed." *Id.* ¶ 118. However, no such language appears in the report.

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On February 27, 2012, Mr. Wilson appeared on CNBC's Fast Money Halftime Show. During the interview, Mr. Wilson predicted that the FDA would approve Qsymia in April 2012. *Id.* ¶ 123. The interviewer asked whether Vivus was seeking a partner to help market the drug, whether it would have to raise capital, and generally about its plans. Mr. Wilson did not address the question about capitalization. He stated that Vivus was looking for a partner for the rest of the world but would launch the product in the United States on its own. *Id.* ¶ 123.

The interviewer then asked, "How do you do that from a financial standpoint?" *Id.* ¶ 124. At that point, Mr. Wilson responded,

> Well, it does take money to launch products, but we have $145 million in the bank at the end of this last calendar year. And we have guided the street that we have plenty of money to go through the approval process and that we will be opportunistic in raising money for the commercialization effort.

*Id.* ¶ 124.

Later in the interview, the interviewer asked again, "Why not raise cash now? Why not raise capital when everyone is clamoring for your stock, people are talking about it?" *Id.* ¶ 125. Mr. Wilson responded that Vivus' position "is that we have adequate money to take us through the approval process through April 17th, and we will raise capital at some time." *Id.* ¶ 125.

### ***3. First Private Call and Purchase (February 2012)***

The same day, Mr. Jasin phoned Mr. Morris "to assure himself that he had not missed any public statements made by Vivus" and "to help him understand how Vivus would maximize Qsymia sales and profits as described in its SEC reports." *Id.* ¶121. During that call, Mr. Morris told him that Vivus was prepared to and capable of launching Qsymia itself. *Id.* ¶ 121. In addition, Mr. Jasin asked Mr. Morris to elaborate on Vivus' statement that CHMP and FDA questions were consistent. *Id.* ¶ 68. Mr. Morris responded that CHMP did not ask Vivus to provide any more information than what Vivus provided to the FDA. *Id.* ¶ 68.

After watching Mr. Wilson's TV appearance and speaking to Mr. Morris, Plaintiffs purchased 100,000 shares of Vivus stock on February 27, 2012 for a total investment of $2,425,008. That day, the stock traded at a high of $25.14 per share before closing at $23.87 per share. *Id.* ¶ 126. The same day, Mr. Wilson sold 50,000 shares and Mr. Marsh sold 47,078 shares.

*Id.* ¶ 131.

#### *4. Form 10-K (February 2012)*

The following day, February 28, 2012, Vivus filed its 10-K. *Id.* ¶ 72, Exh. K. In the form, Vivus described the 120 Day Report in nearly identical terms to its August 2011 Form 10 Q disclosures. *Id.* ¶ 72, Exh. K at 7, ECF 32-7. Again, Vivus noted that the "questions covered a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding . . . heart rate." *Id.* Vivus also again stated that the "120-day questions were consistent with the issues previously raised in the FDA review process." *Id*.

Vivus then described the 180-Day reports:

> The 180-day LOI contained requests for additional information including risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects of Qnexa. In addition, we were asked to discuss the benefit/risk of the different doses of Qnexa, its potential use in different patient populations, and the expected long-term benefit of treatment with [Qsiva]. We are preparing our response, which we plan to submit in the second quarter of 2012. There can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP."

*Id.* ¶ 72. In addition, Vivus stated that "the CHMP . . . may request . . . cardiovascular outcome studies . . . prior to granting approval of Qnexa in the EU." *Id.* ¶ 73, Exh. K at 48. Plaintiffs allege that this filing insufficiently identified the CHMP's concerns. *Id.* ¶ 42.

#### *5. Public Offering (February/March 2012)*

Also on February 28, 2012—the day after Mr. Wilson had stated that Vivus would "raise capital at some time" and Plaintiffs made their purchase—Vivus announced a public offering of 8.5 million shares of common stock. *Id.* ¶ 128. The stock price fell $2.52 to close at $21.26 per share, a drop of 11% from Mr. Wilson's interview. The stock fell an additional 3% after hours. *Id.* ¶ 135.

On February 29, 2012, Vivus released the prospectus for the public offering. *Id.* ¶ 75. Vivus stated that it intended to use the net proceeds from the offering, at least in part, "(viii) to fund the cost of any post-approval Qnexa requirements, including the cost to complete a cardiovascular outcomes study and any additional studies required for Qnexa." *Id.* ¶ 75. In the first week of March 2012, Vivus offered the 8.5 million shares.

***6. Form 10-Q (May 2012)***

On May 7, 2012, Vivus filed its 10-Q. The form stated that Vivus' results may be affected by "(6) our response to questions and requests for additional information including additional pre-clinical or clinical studies from the [EMA and CHMP] of the [MAA] for Qnexa." Vivus also listed "(10) the impact, if any, of the agreement and initiation by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcomes study pre-approval." *Id.* ¶ 76. Plaintiff alleges that Defendants intentionally omitted "the EMA's *direct* demand for cardiovascular safety studies and the EMA's expressed concerns regarding Qnexa's cardiovascular effects" from this filing. *Id.* ¶ 76.

***7. Conference Interviews (May 2012)***

In May 2012, Mr. Morris made public statements regarding the EMA process at three industry conferences. On May 9, 2012, in an interview at the Deutsche Bank Health Care Conference, Mr. Morris stated, "We did get the 180-day letter here and we have submitted our response. So what was in there - all of the requests were very similar to what we had in the United States . . ." *Id.* ¶ 77. The interviewer then asked, "[W]ere there any surprises in the 180 day questions or were they mostly on REMS and labeling?" *Id.* Mr. Morris responded, "Yeah, I would say there is no surprises there, . . . So, but there wasn't anything in that whole list of outstanding issues that we couldn't address with the data or analysis, that we had previously completed for the FDA process." *Id.*

On May 14, 2012, at the JMP Securities Research Conference, Mr. Morris similarly stated: ""[W]e have recently responded to the day 180 list of questions. They, for the most part were the same issues and questions that the FDA had. . . . So, again, nothing really outside the norm here." *Id.* ¶ 78.

On May 15, 2012, at the Bank of America Merrill Lynch Healthcare Conference, Mr. Morris continued to state, "In Europe, we have submitted our response to the day 180 list of issues. For the most part, their questions were the same that the U.S. FDA had." *Id.* ¶ 79.

Plaintiffs allege that these interviews presented "the opportunity to disclose information to Plaintiffs and shareholder [*sic*]" but that Defendants "failed to specify that the additional

information affirmatively requested by the CHMP included a cardiovascular safety study, and attempt[ed] to distract investors by mentioning a possible initiation of a cardiovascular outcomes study pre-approval by one of Vivus' competitors." *Id.* ¶ 80.

**D. FDA Approval, CHMP Rejection, and Related Statements**

***1. Tam on CNBC (July 2012)***

On July 12, 2012, the FDA announced its approval of Qsymia. The FDA directed Vivus to conduct post-approval CV studies. *Id.* ¶ 84.

Six days later, on July 18, 2012, Mr. Tam appeared on CNBC. The host asked about the drug's side-effect profile, Mr. Tam responded:

> "I think it's actually very important for patients to use the drug properly, and for physicians to educate patients in terms of how to use the medication. Keep in mind that both of these drugs that are in Qsymia are drugs that have been approved by FDA and have been used by millions and millions of patients at much much higher doses. Qsymia is actually a combination of low doses of two drugs that have been used. So we are very very comfortable with the safety profile of Qsymia."

*Id.* ¶ 83(a). On the same theme, the host asked,

> "What will the label list [ ] in terms of precautions and side effects? Any . . . heart related red flags? Anything . . . from worries in the past about obesity drugs? And . . . the saga of almost any obesity drug, there always seems to be something you need to worry about?"

*Id.* ¶ 83(b). Mr. Tam responded,

> Yes, it is important for patients who are pregnant to not use Qsymia . . . that's an important consideration . . . some of the common side effects associated with Qsymia are dry mouth, constipation. So these are . . . mild in nature . . . again patients with Qsymia can actually down titrate, if that's necessary.

*Id.* ¶ 83(b). Plaintiffs allege that Mr. Tam knew or should have known these statements were false or misleading because of the FDA's requirement of post-approval CV studies and the EMA's alleged requirement of pre-approval CV studies. They contend that he should have mentioned the CV side effects. *Id.* ¶ 8.

The same day, Defendants sold Vivus stock. Mr. Wilson exercised 100,000 options to

purchase common stock and sold those shares at $30.36 per share for net proceeds of $3,036,000. This represented 46% of Mr. Wilson's remaining Vivus stock. *Id.* ¶ 157(a). Mr. Morris exercised the entirety of his remaining 25,000 options to purchase common stock and sold those shares at $30.36 per share for net proceeds of $759,000. *Id.* ¶ 157(b). Mr. Tam exercised 25,000 options to purchase common stock and sold those shares at $30.95 per share for net proceeds of $773,750. This represented 40% of Mr. Tam's remaining Vivus stock. *Id.* ¶ 157(c). Other Vivus executives made similar sales, exercising tens of thousands of options for proceeds ranging from $1,098,759 to $303,600. *Id.* ¶ 157(d)-(g). Each executive sold at a price that was near the stock's historical high of $31, also reached that day.

***2. Second Private Call and Purchase (July 2012)***

On July 23, 2012, Mr. Jasin again contacted Mr. Morris "to assure himself that he had not missed any public statements made by Vivus." *Id.* ¶ 85. Mr. Jasin asked about the status of the MAA in Europe. Mr. Morris allegedly responded that there was nothing new to report as nothing negative, positive, or unusual had happened but that it was "looking real good for approval." *Id.*

From April 20, 2012 to July 30, 2012, Plaintiffs purchased more than 192,000 shares of stock. *Id.* ¶ 86. This included a purchase of 13,067 shares on July 30, 2012. *Id.*

From July 18, 2012 to August 1, 2012, the stock price fell from the high of $31 per share to just under $20 per share—a 35% decrease in price. *Id.* ¶ 159.

***3. Press Release (September 2012)***

On September 21, 2012, Vivus issued a press release announcing that "based on preliminary feedback from the [CHMP], the company expects an opinion recommending against approval of the [MAA] for Qsiva." *Id.* ¶ 88. The press release alerted the public that Vivus expected the CHMP to issue its formal decision in October 2012. *Id.* If the decision was negative, "and depending on the nature of the objections, the company will either resubmit the MAA at a later date or appeal this decision and request re-examination by the CHMP." *Id.* That day, the stock closed at $21.00 per share, down 11.5% from the previous close of $23.72. *Id.* ¶ 90.

***4. Third Private Call and Purchase (September 2012)***

Also on September 21, 2012, Mr. Jasin called Vivus and believes he spoke to Mr. Morris

about the press release. *Id.* ¶ 89. Mr. Morris allegedly explained that Vivus was going to work with the CHMP to address the CHMP's concerns. *Id.*

On September 24, 2012, Mr. Jasin emailed Mr. Morris to ask whether the European regulators had explicitly stated that Qsiva would not be approved, or whether the result had only been implied. *Id.* ¶ 91. Mr. Morris allegedly responded by email that the rejection was Vivus' "general impression" based on recent meetings. *Id.*

From September 21 to October 18, 2012, Plaintiffs purchased stocks in reliance on their belief that the CHMP's concerns were of the kind that Vivus could resolve. *Id.* ¶ 99.

***5. CHMP Refusal (October 2012)***

On October 18, 2012, the CHMP issued an opinion refusing to grant market authorization for Qsiva. *Id.* ¶ 92. Nineteen of the 29 members voted against approval. *Id.* ¶ 92. In the opinion, the CHMP identified the following as issues that had not been sufficiently studied: the stability of PHEN and TPM beads stored in bulk in order to support starting the drug's shelf-life at the time of capsule filling; Qsiva's efficacy on older subjects and patients with cardiovascular disease; the long-term CV safety of Qsiva; the frequency of adverse psychiatric and cognitive effects; the teratogenic risk of the product in a real-life setting; and the difficulty of minimizing off-label uses. *Id.* ¶ 93. Vivus announced that it would appeal the decision and seek a re-examination. *Id.* ¶ 95.

That day, the stock price declined by $1.24 from $22.30 to $21.06 per share. *Id.* ¶ 95. Plaintiffs continued to purchase Vivus stock, again relying on their belief that Vivus could resolve the CHMP's concerns. *Id.* ¶ 99.

***6. Wilson Meeting with Analysts***

Vivus' launch of Qsymia in the United States did not meet expectations. *See id.* ¶¶ 141-144. On November 15, 2012, Mr. Wilson met with analysts and took responsibility for mismanaging expectations for Qsymia. *Id.* ¶ 141. News outlets reported that Mr. Wilson "said [the disappointing sales of Qsymia] was his mistake, he shouldn't have let it happen, and that he plans to do a much better job at outlining for investors what the company believes the continuation of the launch will look like." *Id.* ¶¶ 142, 143.

***7. CHMP Refusal Confirmed***

On February 21, 2013, after re-examination, the EMA confirmed its rejection of Qsiva. *Id.* ¶¶ 16, 96. Vivus issued a press release stating, "After considering the grounds for [re-examination of the opinion], CHMP again declined the marketing authorization on February 21, 2013. In its consideration of the Qsiva MAA, CHMP indicated that a pre-approval cardiovascular outcomes trial would be necessary to establish long-term safety." *Id.* ¶ 96, Exh. O, ECF 32-7.

***8. Proxy Fight***

On June 4, 2013, First Manhattan Co. ("FMC"), an investment advisory firm and the beneficial holder of approximately 9.9 percent of the outstanding shares of Vivus, filed definitive proxy materials with the SEC seeking to have nine of its nominees elected to Vivus' Board at the next annual meeting of stockholders. *Id.* ¶ 146. FMC believed Vivus stock was undervalued due to the failures by the company's leadership to secure a U.S. commercial partnership, to properly plan and execute the Qsymia launch, and to obtain approval for Qsiva in Europe. *Id.* ¶ 147.

FMC eventually filed suit against Vivus' board of directors and Vivus itself. *Id.* ¶ 149. The suit settled, resulting in Vivus reconstituting its board and several of its directors, including Mr. Tam and Mr. Wilson, resigning. *Id.* ¶¶ 151-52.

Following the proxy fight, Mr. Jasin spoke to one of Vivus' new directors, Dr. Samuel Colin. *Id.* ¶ 153. Dr. Colin told Mr. Jasin that he "wouldn't believe what we've uncovered since getting there" but refused to elaborate. *Id.*

On September 20, 2013, Vivus issued a press release announcing that it had submitted a request for scientific advice regarding the use of a pre-specified interim analysis from a particular cardiovascular outcomes trial to support resubmission of the MAA for Qsiva in Europe. *Id.* ¶ 97.

**E. This Suit**

On July 18, 2014, Plaintiffs initiated this securities fraud action, alleging four sets of misrepresentations or omissions. The Court dismissed Plaintiffs' First Amended Complaint ("FAC") for failure to adequately allege material misrepresentations and scienter. Of the four misrepresentations Plaintiffs initially alleged, Plaintiffs have re-alleged only two—those regarding the CHMP's concerns and the timing of the stock offering in 2012. With regard to those allegations, the Court's First Dismissal Order noted that Plaintiffs' allegations about the CV study

were strongest, but that the FAC's focus on disclosure of the Co-Rapporteur's 80 Day Report was insufficient because the report represented an individual committee member's position and constituted an interim comment. *See* First Dismissal Order at 14, ECF 31. With regard to the additional stock offering allegations, the Court concluded that Plaintiffs failed to show that Mr. Wilson's statement that Vivus would raise capital "at some time" could not truthfully encompass an announcement of a public stock offering the following day and that they also failed to allege scienter. *Id.* at 15-16.

Plaintiffs now allege that they relied on Defendants' misrepresentations and omissions when deciding to purchase Vivus stock. Specifically, Plaintiffs allege that Defendants misrepresented or omitted: (1) the CHMP's requirement of pre-approval cardiovascular clinical studies for Qsiva; (2) the CHMP's grave concerns about Qsiva's cardiovascular, psychiatric, and cognitive effects, the necessity of further stability studies, and the difficulty Vivus would have in minimizing "off-label" or unapproved uses; and (3) Vivus' plan to announce a public offering on February 28, 2012. Plaintiffs allege that, had they known the truth, they would not have purchased Vivus stock and would have liquidated their Vivus holdings on July 18, 2012 or as soon thereafter as possible. SAC ¶¶ 100-01. The Court now considers Plaintiffs' amended pleadings.

## II. LEGAL STANDARD

### A. Rule 12(b)(6)

"A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted 'tests the legal sufficiency of a claim.'" *Conservation Force v. Salazar*, 646 F.3d 1240, 1241-42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)). When determining whether a claim has been stated, the Court accepts as true all well-pled factual allegations and construes them in the light most favorable to the plaintiff. *Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011). However, the Court need not "accept as true allegations that contradict matters properly subject to judicial notice" or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (internal quotation marks and citations omitted). While a complaint need not contain detailed factual allegations, it

"must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Dismissal without leave to amend is improper unless it is clear . . . that the complaint could not be saved by any amendment." *Krainski v. Nevada ex rel. Bd. of Regents of Nevada Sys. of Higher Educ.*, 616 F.3d 963, 972 (9th Cir. 2010).

**B. Rule 9(b) and the PSLRA**

In addition, a plaintiff asserting a private securities fraud action must meet the heightened pleading requirements imposed by Federal Rule of Civil Procedure 9(b) and the PSLRA. *See In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *see also In re VeriFone*, 704 F.3d at 701. Similarly, the PSLRA requires that the complaint "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading . . . ." 15 U.S.C. § 78u–4(b)(1)(B).

The PSLRA further requires that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u–4(b)(2)(A). "To satisfy the requisite state of mind element, a complaint must allege that the defendant[ ] made false or misleading statements either intentionally or with deliberate recklessness." *In re VeriFone*, 704 F.3d at 701 (internal quotation marks and citation omitted) (alteration in original). The scienter allegations must give rise not only to a plausible inference of scienter, but to an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

"The relevant inquiry is 'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *In re VeriFone*, 704 F.3d at 701 (citing *Tellabs*, 551 U.S. at 323). "[A] dual analysis"—that is, first considering allegations individually and then in combination—"remains permissible so long as it does not unduly focus on the weakness of individual allegations to the

exclusion of the whole picture." *Id.* at 703. "To avoid potential pitfalls that may arise from conducting a dual analysis," a court can instead "approach [a] case through a holistic review of the allegations . . . [without] simply ignor[ing] the individual allegations and the inferences drawn from them." *Id.*

## III. DISCUSSION

### A. Section 10(b) and Rule 10b-5

The elements of a private securities fraud action under Section 10(b) and Rule 10b-5 are: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1206 (9th Cir. 2016) (quoting *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804 (2011)). Here, Defendants argue that Plaintiffs have failed to plead facts creating a strong inference of falsity or scienter.

To satisfy the first element, "[t]he complaint must plead specific facts indicating why any alleged misrepresentation was false or any omission rendered a representation misleading." *Lloyd*, 811 F.3d at 1206 (citing 15 U.S.C. § 78u–4(b)(1)). A statement or omission is material when "there is 'a substantial likelihood that the disclosure of the [] fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). However, "[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not." *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Therefore, "to be actionable under the securities laws, an omission [or misrepresentation] . . . must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Id.*

To plead scienter adequately, the complaint must "state with particularity facts giving rise to a strong inference that the . . . defendants engaged in knowing or intentional conduct." *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008) (internal citation and quotation marks omitted). The inference of scienter must be "at least as compelling as any opposing inference of

nonfraudulent intent." *Tellabs*, 551 U.S. at 314.

Defendants argue that not one of the alleged omissions or misrepresentations satisfies either the material misrepresentation standard or the scienter standard. The Court considers each alleged omission or misrepresentation in turn.

**1. Statements Regarding Pre-approval Cardiovascular Study**

Defendants first challenge Plaintiffs' allegations that, through their SEC filings, shareholder calls, and direct communications with Plaintiffs, Defendants created the false impression that a pre-approval CV study may be, but was not explicitly, required for EMA approval. Mot. at 10-13. Defendants agree that they communicated the possibility rather than the certainty of such a requirement, but they argue that this accurately reflected the facts: they contend that only one member had stated that a CV study should be required before approval and that he did so in an interim report. Mot. at 11. Meanwhile, they argue, the full committee's position remained open throughout the EMA process. *Id*. Thus, Defendants challenge both the falsity and the materiality of these allegations.

The Court begins with Plaintiffs' allegations regarding the CV study as a pre-approval requirement. Plaintiffs allege that a pre-approval CV study requirement was stated as a certainty rather than a probability in the Co-Rapporteur's 80 Day Report, the full Committee's 120 Day Report, the rapporteurs' September 2011 meeting with Vivus, the Rapporteurs' 180 Day Joint Report, and the full Committee's 180 Day Report. For example, the Co-Rapporteur's 80 Day Report stated, "the Co-Rapporteur considers that an international large scale simple trial . . . should be required **<u>pre-approval</u>** . . . on cardiovascular events . . ." and found Vivus' proposal of performing a post-approval study unacceptable. SAC ¶ 49, Exh. F at 62, 70 (emphasis in original). The full Committee's 120 Day Report stated that "for a positive benefit/risk balance, the Applicant needs . . . the performance of a CV safety study . . . before approval." *Id.* ¶ 52(e), Exh. C at 61. The Rapporteurs' 180 Day Joint Report stated that "[t]he lack of a CV safety study . . . needs to be further justified," *id.* ¶ 53(b), Exh. G at 66, and the CHMP similarly wrote in its 180 Day Report that "the applicant should further justify the lack of . . . cardiovascular safety study before approval." *Id.* ¶¶ 54(d), 55, Exh. H at 61. On this basis, Plaintiffs challenge statements Defendants

made that the EMA "may" require a pre-approval study and comparing the data necessary for the EMA process to that which the FDA, which did not request a pre-approval study, had required. [6]

Defendants argue that this record does not support Plaintiffs' allegations that the CHMP "required" or "demand[ed]" a CV safety study. Mot. at 11 (citing SAC ¶¶ 50, 70, 74-76). First, with regard to the Co-Rapporteur's 80-Day Report, Defendants argue that the Report constituted only the Co-Rapporteur's position and therefore could not have established a requirement—particularly not when the Rapporteur's Report, issued the same day as the Co-Rapporteur's Report, identified the increase in heart rate as only a "limited concern." Mot. at 11 (quoting SAC Exh. P at 149). Defendants next contend that the full Committee's 120 Day Report also did not communicate a pre-approval requirement because it was instead a fluid interim regulatory development. Defendants argue that the CHMP's 180 Day Report shows this to be the case because it asked Vivus to present a CV study *or* justify why one was not necessary, thereby communicating that a CV study was not necessarily required prior to approval. Mot. at 11-12.

In addition, Defendants argue that securities law does not require them to disclose every single regulatory opinion they receive, as long as the disclosures they make do not misrepresent those that they do not mention. To support this argument, Defendants rely on *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F. 3d 869, 879 (9th Cir. 2012). In *Rigel Pharm.*, the Ninth Circuit considered allegations that a pharmaceutical company misrepresented the side effects of a drug by failing to disclose certain concerns in its initial press release. The Ninth Circuit found these allegations insufficient on falsity grounds because the company had explicitly labeled its initial report "'*key* safety results,'" *id.* at 880 (emphasis in original), and because future disclosures, while more extensive, were not inconsistent with the initial report, *id.* at 881. The court noted that "section

[6] Specifically, Plaintiffs challenge: 1) Vivus' May 6, 2011 Form 10-Q filing, which states that the EMA "may request . . . cardiovascular outcome studies prior to granting approval," SAC ¶ 50; 2) the November 2011 earnings call and Form 10-Q filing, which failed to disclose the study as an explicit requirement and falsely compared the EMA process to Vivus' discussions with the FDA, which allegedly never considered a pre-approval CV study, *id.* ¶¶ 58-63; 3) Mr. Morris' May 2012 statements that the EMA had not raised any issues that Vivus could not address with the data or analysis completed for the FDA process and that things were "looking real good for approval" in July 2012, *id.* ¶¶ 68, 77-79, 85; 4) Vivus' February and May 2012 SEC filings that stated only that a CV study "may" be required pre-approval, *id.* ¶¶ 73, 76; and 5) Mr. Tam's omission of the alleged CV study requirement during a July 2012 CNBC interview, *id.* ¶¶ 83-84.

10(b)(5) and Rule 10b–5 do not create an affirmative duty to disclose any and all material information; section 10(b) and Rule 10b–5 prohibit only misleading and untrue statements, not statements that are incomplete." *Id.* at 880, n.8 (citing *Matrixx*, 131 S.Ct. at 1321–22.) In the context of side effects, "as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *Id.*

While Plaintiffs oppose Defendants' contention that they did not need to report "complete" information throughout the EMA regulatory process, the cases they cite stand for the same proposition as do the cases cited by Defendants—that incomplete reporting is actionable where it "create[s] an impression of a state of affairs that materially differ[s] from what actually existed." Opp. at 12 (quoting *Neborsky v. Valley Forge Composite Techs., Inc.*, 2014 U.S. Dist. LEXIS 104681 at * 1 (S.D. Cal. July 29, 2014)).

Defendants make a similar argument with regard to materiality. Defendants argue that they did not have a duty to disclose the full contents of the 80 and 120 Day Reports because they were interim regulatory developments. Mot. at 12-13. For this argument, Defendants rely on *In re Genzyme Corp*., which the Court considered and cited with approval in its First Dismissal Order.

In *Genzyme*, a class of investors sued a bio-pharmaceutical company for failing to disclose, among other things, that the FDA had sent the company an observation form that was critical of the company's manufacturing process for a new drug. *In re Genzyme Corp*., No. CIV. 09-11299-GAO, 2012 WL 1076124, at *3 (D. Mass. Mar. 30, 2012). As part of its scienter analysis, the court concluded that the form was "of doubtful materiality." *Id.* at *10. The court explained that because the observations "'do not represent a final agency determination,' they are necessarily interim statements, subject to revision." *Id.* The court determined that securities law "simply cannot" view "every critical comment by a regulatory agency—even about matters as important as good manufacturing practices . . . as material." *Id.* Otherwise, "a flood of data . . . would overwhelm the market and would ironically be, in the end, actually uninformative." *Id.*

As before, the Court finds *Genzyme* persuasive on the question of the materiality of the

statements made in the 80 and 120 Day Reports. Though *Genzyme* considered a different process (warning observations and letters) by a different regulatory agency (the FDA) and, as Plaintiffs correctly note, the warning letters did not stop FDA approval, *see* Opp. at 11 n.5, many of the principles underlying the court's finding of immateriality are present here. Like the FDA's observation form and warning letter, the EMA's 80 and 120 Day Reports "do not represent a final agency determination" and are therefore "necessarily interim statements, subject to revision." 2012 WL 1076124, at *10. In addition, while they may "reflect [the CHMP's or Co-Rapporteur's] position on the matter, [they] do not commit the [EMA] to taking [regulatory] action." *Id.*

Having reviewed the reports from the EMA process, the Court agrees with Defendants: Plaintiffs have failed to sufficiently allege falsity regarding the CV safety study requirement or materiality regarding the statements in the 80 and 120 Day Reports.

Throughout the CHMP process, the committee never communicated that a CV study was a pre-approval requirement. The Co-Rapporteur's 80-Day Report did not establish such a requirement. Rather, it presented the opinion of a sole CHMP member—and one that, importantly, the Rapporteur did not share. Plaintiffs' allegation that rapporteurs "carry a strong voice in leading the voting process," SAC ¶ 45, does not correct this deficiency because the two rapporteurs did not agree. Similarly, the 120 Day Report did not require a pre-approval CV study. Instead, it constituted an interim statement that could—and did—change over the course of the regulatory process. As shown by the CHMP's 180 Day Report, the Committee gave Vivus the alternative of justifying why no pre-approval CV study was needed. And some members apparently found the justification Defendants provided to be a sufficient replacement for the study: 10 of the 29 CHMP members voted in favor of approving Qsiva.

Thus, far from being misleading, Defendants' statements that the CHMP "may" request a CV study "prior to granting approval" were accurate: the issue remained an open question until the CHMP confirmed its refusal of Qsiva's MAA in Europe and finally "indicated that a pre-approval cardiovascular outcomes trial would be necessary to establish long-term safety." SAC ¶ 96; Exh. O (quoting Vivus press release). As in *Rigel*, though investors may have preferred to have more information regarding the reports, section 10(b)(5) and Rule 10b-5 do not require such full

disclosure as long as that which is disclosed does not misrepresent the remaining contents. The Court also agrees with Defendants that the 80 Day and 120 Day Reports did not represent material developments that needed to be disclosed in full. Instead, as discussed above, they constituted steps along a known and fluid regulatory process.

Similarly, Defendants' statements about the similarity between the data necessary for the FDA and EMA processes were neither false nor misleading. Instead, the statements accurately communicated the possibility that Defendants could get approval by justifying the lack of a CV study. For example, the CHMP could have agreed, as the FDA had, that a post-approval CV study was sufficient (notwithstanding the Co-Rapporteur's opposition to this proposal in his 80 Day Report, for the reasons discussed above).

Furthermore, Defendants correctly note that, prior to the challenged statements, Vivus had disclosed to investors that the EMA might require a pre-approval CV study though the FDA had not. Mot. at 18. *See, e.g.*, RJN Exh. 1 at 48 (May 2011 Form 10-Q disclosing possibility of pre-approval CV study requirement); *id.* Exh. 2 at 18 (August 2011 Form 10-Q disclosing that CHMP may request a CV study prior to approval though the FDA had not); SAC ¶ 73 (describing similar disclosure in February 2012 Form 10-K). Given these disclosures noting the differences between the two processes and explicitly stating that the CHMP might require a pre-approval study, Plaintiffs have failed to allege that there was "a substantial likelihood" that Mr. Wilson's statements regarding the similarities between the two processes "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *See Matrixx*, 563 U.S. at 38. Instead, even taking Mr. Wilson's statements into account, a reasonable investor would have known that a CV study might be required before approval.

Finally, Defendants argue that the SAC also fails to plead scienter with regard to the CV study for largely the same reasons, and the Court agrees. In *Genzyme*, the court explained that "if the materiality of a particular fact is in question, that 'tends to undercut' an inference that a defendant acted with the requisite scienter." *Genzyme*, 2012 WL 1076124 at *8 (quoting *City of Dearborn Heights Act 345 Police & Fire Retirement System v. Waters Corp.*, 632 F.3d 751, 757 (1st Cir. 2011)). Here, not only is the materiality of a particular "fact" in question, but Plaintiffs

have failed to allege sufficiently that their theory—specifically, that the CHMP required a pre-approval CV study through the 80 and 120 Day Reports—is a fact at all.

While, with the benefit of hindsight, Plaintiffs can now say that the CHMP required a CV study pre-approval, they have failed to allege that Defendants knew this to be the case at the time of their challenged statements. Rather, the allegations and supporting documentation establish that, following the 80 Day Reports, Defendants knew that the rapporteurs took conflicting positions on whether or not a CV study would be required before approval. Following the 120 Day Report, the Defendants may have known that the CHMP was leaning towards requiring a pre-approval study, but they also knew that the 120 Day Report reflected an interim position that Defendants had the opportunity to combat. Much like the FDA form in *Genzyme*, the positions in a 120 Day Report are "necessarily interim statements, subject to revision." *Id.* at *10. In fact, as shown by the 180 Day Reports, the CHMP's position did change. The 180 Day Reports gave Defendants the opportunity to persuade the Committee that no pre-approval study was necessary.

Thus, Defendants' statements that a pre-approval study "may" be required accurately reflected their knowledge at the time. Therefore, Plaintiffs have failed to "state with particularity facts giving rise to a strong inference that . . . defendants engaged in knowing or intentional conduct." *See S. Ferry LP*, 542 F.3d at 782. Instead, an inference of nonfraudulent intent—specifically, that Defendants intended to accurately reflect the CHMP's concerns—is more compelling than the inference of fraudulent and knowing intent. This is further supported by Defendants' disclosures regarding the burden such a study requirement could impose, both for the chances of approval and for Vivus' finances more broadly. Far from attempting to brush the possibility under the rug, Defendants fully disclosed the potential gravity.

In addition, the fluidity of the approval process and the divergent opinions expressed in the interim reports negates any inference of scienter. *See Genzyme*, 2012 WL 1076124 at *10. Thus, the Court finds that the pre-approval requirement allegations have failed to plead falsity, materiality, and scienter.

**2. Statements Regarding Other CHMP Concerns**

The Court now turns to Plaintiffs' allegations regarding Defendants' misrepresentation of

the EMA's concerns about Qsiva's adverse CV, psychiatric, and cognitive effects; the difficulty of minimizing off-label uses; and the lack of stability studies for the drug. Defendants argue that these allegations also fail on falsity, materiality, and scienter grounds.

Again, the Court begins with Plaintiffs' allegations. Plaintiffs allege that the CHMP communicated its concerns about Qsiva's CV safety, separate from the CV study requirement discussed at length above, in its 120 Day Report and the Rapporteurs' 180 Day Joint Report. The 120 Day Report stated that "CV safety in the full target population needs to be further discussed," the lack of a withdrawal study "is a deficiency when deciding on optimal duration of the treatment," and "the CV safety of PHEN/TPM should be further evaluated before approval." SAC ¶ 52(a)-(c). The Joint Report communicated similar concerns. *Id.* ¶ 53.

Plaintiffs additionally allege that the CHMP communicated serious concerns about Qsiva's psychological and cognitive effects through the Rapporteurs' 180 Day Joint Report and the CHMP 180 Day Report. The Rapporteurs stated that the lack of proposed risk minimization activities for such effects "needs to be further justified" and that Vivus "should discuss the possibility" of including cognitive disorders in a study. *Id.* ¶ 106. The CHMP listed cognitive and psychiatric disorders as target adverse events. *Id.* ¶ 113. Plaintiffs also point to the 80 Day Reports, in which the Rapporteur identified these as "important identified risks" and the Co-Rapporteur stated that Vivus should analyze the psychiatric effects of the drug. *Id.* ¶¶ 108, 110.

To allege that the CHMP was concerned that minimizing off-label uses would prove difficult, Plaintiffs point to the Rapporteur's 80-Day position that such use is "a serious concern," *id.* ¶ 115, and that Vivus should discuss the need for risk minimization or justify why it is not needed. *Id.* ¶ 117. Plaintiffs also allege that the CHMP expressed similar concerns in its 180 Day Report, which lists off-label use in its risk management plan. *Id.* ¶ 118, Exh. H at 53.

With regard to stability studies, Plaintiffs allege that the CHMP's October 2012 opinion refused to grant approval on the basis, in part, of insufficient "stability studies on PHEN beads and TPM beads stories in bulk in order to support a start of the shelf-life." *Id.* ¶¶ 39, 42, 93, 103-105. However, as Defendants argue, Plaintiffs fail to offer allegations regarding when or how Vivus became aware of these concerns and, therefore, how any omission could have been intentionally

misleading. *See* Mot. at 19. The fact that the CHMP listed this as a concern in its ultimate rejection of Qsiva's does not suffice to allege falsity.

**a. Forward-Looking Statements**

Plaintiffs challenge Defendants' forward-looking statements, such as Mr. Morris' statement that things were "looking real good for approval," *id.* ¶ 85, and Vivus' statement in its SEC filings that "[t]here can be no assurance that our response will be adequate or that our MAA will be approved by the CHMP," *id.* ¶ 72, for failing to identify the gravity of the CHMP's concerns about Vivus' side effects, stability, and potential for off-label use.

Specifically, Plaintiffs first claim that Defendants misrepresented the CHMP's concerns by failing to identify them in Vivus' Form 8-K, issued on April 4, 2011. Because Plaintiffs have not alleged that the CHMP issued any opinions identifying concerns before that—rather, the earliest report Plaintiffs cite was issued to Vivus a week later—Defendants could not have misrepresented or omitted any CHMP concerns in the Form 8-K. Accordingly, this allegation fails to support falsity.

In addition, Plaintiffs generally allege that Vivus insufficiently disclosed the CHMP's concerns about Qsiva's side effects, stability, and off-label uses in its annual 10-K and quarterly 10-Q forms, *see, e.g.*, SAC ¶ 42, and also challenge Mr. Morris' statement to Mr. Jasin on July 23, 2012 that things were "looking real good for approval," *id.* ¶ 85. Defendants argue that Plaintiffs cannot challenge these forward-looking statements because they are protected by a PSLRA safe harbor. Mot. at 15. The safe harbor for forward-looking statements, 15 U.S.C. § 78u-5(c)(1)(A)(i), provides that, with certain exceptions, a misleading statement or omission in a "forward-looking statement, whether written or oral," is not actionable if the statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." Defendants argue that this safe harbor protects them here, as Vivus advised the market repeatedly and in great detail of the risk that the EMA might decide against approval. Thus, they argue, they cannot be liable for the particular risks they chose to mention or highlight in the forward-looking disclosures.

To support this argument, Defendants rely on *Zeid v. Kimberley*, 930 F. Supp 431, 437 (N.D. Cal. 1996). In *Zeid*, the plaintiffs alleged that a company released misleading warnings and disclaimers in its Form 10-Qs. 930 F. Supp. at 437. The filings stated that the company's financial results may vary significantly due to several factors, but the plaintiffs argued that the company "should not have stated that certain adverse factors *may* [a]ffect the financial statements, but rather that it should have said they *are* [a]ffecting [the] business." *Id.* The court dismissed these arguments as "absurd," noting that "warnings regarding potential adverse factors are not actionable as a matter of law." *Id.* In addition, the court found that the Plaintiffs did not assert that the warnings were wrong, but rather that they should have been more specific. The Court dismissed the claims with prejudice because "Section 10(b) and Rule 10b–5 are designed to protect against false and misleading statements, not statements that are too abstract." *Id.*

Defendants offer additional cases that reach the same result. For example, one court in this district dismissed allegations that certain disclosures of "risk factors" in quarterly and annual SEC filings were misleading "to the extent plaintiffs contend defendants should have stated that the adverse factors 'are' affecting financial results rather than 'may' affect financial results" because "these statements constitute defendants' cautionary statements and are not actionable." *In re LeapFrog Enterprises, Inc. Sec. Litig.*, 527 F. Supp. 2d 1033, 1048 (N.D. Cal. 2007). The court was additionally persuaded by the fact that the plaintiffs had failed to allege that any of the disclosures were affirmatively false or misleading when made. Defendants argue that the same result should apply here.

Plaintiffs respond that stating a known risk as a possibility is actionable. They rely on *In re Nuvelo, Inc.*, 668 F. Supp. 2d 1217 (N.D. Cal. 2009), which held that allegations that a biopharmaceutical company had failed to disclose the stringent statistical standard it knew the FDA required for approval of its drug sufficed to plead misrepresentation of the likelihood of the drug's success. *Id.* at 1221. The court found that, because the amended complaint alleged that "defendants misled investors by omitting to disclose a material *risk* that [the study] would fail," they satisfied the falsity and materiality pleading requirement. *Id.* at 1230. (emphasis in original).

The Court finds this case inapplicable here. In *Nuvelo*, the drug company knew with

certainty that the FDA would require a more stringent p-value for its analysis and did not disclose that fact, even as a risk. In contrast, here, Plaintiffs have failed to allege that Defendants knew that the EMA would require more than they provided in response to the 180 Day Reports regarding cardiovascular, cognitive, and psychiatric effects and minimizing off-label use. Much like for the CV study, the CHMP stated only that these concerns needed to be further justified or discussed—not that they would explicitly bar approval if they were not eliminated, as would failure to satisfy the p-value in *Nuvelo*. Furthermore, in contrast to the *Nuvelo* defendants, Defendants in this case disclosed the CHMP's concerns as risks, even though they did not know the concerns to be certain bars to approval.

Plaintiffs additionally rely on *In re Connetics Corp. Sec. Litig*., No. C 07-02940, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008), in which investors challenged a pharmaceutical company developing a dermatological product for failing to disclose the fact that a pre-clinical test on mice resulted in cancerous skin tumors on more than half of the animals and that the FDA had identified these results as a "serious issue" for the drug's approval. *Id.* at *1. The investors additionally alleged that the defendants reported that the study had yielded "positive" results and that the FDA "was interpreting some of the results . . . differently." *Id.* at *1.

In light of those facts, the court found the defendants' statements that "we're very confident in the data set we've got" and that "[w]e believe it's one of the strongest data sets for an acne products [*sic*] submitted to the FDA" to be actionable. *Id.* at *7. The court explained that the speaker knew the troubling results of the study and had been advised that the FDA had never approved a drug with such results. *Id.* at *7. Therefore, the speaker was "aware of undisclosed facts tending to seriously undermine the accuracy of the statement." *Id.* (quoting *In re Apple Computer Sec. Litig.*, 886 F. 2d 1109, 1113 (9th Cir. 1989)).

In addition, the court found that the defendants' failure to disclose the "seriousness of the [FDA's] concerns" was also actionable. The court based this finding on allegations that "defendants approved a ban on trading Connetics securities by people who had attended the [FDA] conference call or were involved in preparing regulatory submissions for [the drug]." *Id.* at *7-8.

In contrast, here, Plaintiffs neither allege that a study exists, justifying any of the EMA's

allegedly material concerns, nor do they provide allegations—such as those regarding the trading ban in *Connetics*—to suggest that the EMA's concerns were more serious than Defendants made them out to be in their statements.

As a result, the Court again agrees with Defendants. Here, the cautionary statements Defendants made in their SEC filings were non-actionable under the PSLRA's safe harbor. Furthermore, the statements were not misleading: they disclosed the CHMP's requests for "risk minimization activities to address various issues relating to cardiovascular, neuropsychiatric and potential teratogenic effects." SAC ¶ 72 (quoting February 2012 Form 10-Q). As in *Zeid* and *LeapFrog*, Plaintiffs have therefore failed to allege that these warnings were baseless or wrong.

To the extent that Plaintiffs challenge the disclosures for failing to mention the risk of off-label use, the Court again finds that the challenged portions of the SEC filings—specifically, the statements regarding the potential effects of the CHMP's concerns on EMA approval of Qsiva—are non-actionable, forward-looking statements. In addition, *Rigel Pharm* is instructive on this point. As discussed above, in that case, the Ninth Circuit found that a drug company's failure to disclose every negative side effect was insufficient to allege falsity. *In re Rigel Pharm.*, 697 F. 3d at 880-81. "[A]s long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial"—or, in this case, regulatory body's concern—"even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *Id.* at 880 n.8. Thus, while Vivus may not have addressed every single CHMP concern, the Court finds that none of the allegedly omitted issues were inconsistent with Defendant's disclosures. In addition, as the court explained in *Genzyme*, requiring disclosure of every single concern would have resulted in "a flood of data [that] would overwhelm the market and would ironically be, in the end, actually uninformative." 2012 WL 1076124, at *3.

The Court additionally agrees with Defendants that Plaintiffs have failed to allege scienter for these claims. As above, the Court finds that the SAC's failure to plead that the disclosure was misleading, insufficient, or related to material information translates into a failure to sufficiently allege that "defendants engaged in knowing or intentional conduct." *S. Ferry LP*, 542 F.3d at 782

(9th Cir. 2008).[7]

**b. Mr. Tam's CNBC Appearance**

Plaintiffs also claim that Defendant Tam "downplayed" the CV concerns during his July 2012 CNBC appearance by failing to identify increased heart rate as a side effect. SAC ¶¶ 8, 84. The host asked: "What we always ask, Peter, is the side-effect profile . . . do you need to be careful when you use an obesity drug, still at this point?" Mr. Tam responded that, though patients needed to use the drug properly and physicians needed to educate them on how to do so, "we are very very comfortable with the safety profile of Qsymia." The host later followed up, "What will the label list . . . in terms of precautions and side effects? . . .[A]ny heart related red flags? Anything . . . from worries in the past about obesity drugs?" *Id.* ¶ 83. Tam responded that pregnancy-related concerns are an "important consideration" and listed dry mouth and constipation as "some of the common side effects," but did not identify CV concerns.

Defendants first argue that Mr. Tam's statement was not a misrepresentation because it was a direct answer to the specific question about labeling. Defendants contend that CV concerns like increased heart rate would not be listed on a drug's label. Mot. at 14.

The Court finds this argument entirely unpersuasive. The Court notes that Defendants argue that Plaintiffs "do not allege" that increased heart rate appears on Qsymia's label as a side effect, *id.*, but they do not go so far as to state that no such side effect is listed. And this is likely for good reason: an increased heart rate is precisely the sort of side effect that one would expect to see on a drug label. *See, e.g.*, *Kovtun v. VIVUS, Inc.*, No. C 10-4957 PJH, 2012 WL 4477647, at *9 (N.D. Cal. Sept. 27, 2012), *aff'd sub nom. Ingram v. VIVUS, Inc.*, 591 F. App'x 592 (9th Cir. 2015) (noting that cardiovascular side effects are identified on the label for phentermine); *cf. Am. Medicinal Products v. Fed. Trade Comm'n*, 136 F.2d 426, 427 (9th Cir. 1943) (upholding FTC order requiring drug company to cease and desist from selling purported obesity remedy due, in part, to it causing increased heart rate).

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[7] Defendants additionally argue that Plaintiffs cannot challenge any form filed before the November 2011 10-Q because, before Plaintiffs made their first purchase, the earlier forms were superseded by later filings and Plaintiffs therefore could not have relied on the earlier forms. Mot. at 16-17 n.5. The Court does not reach this argument.

Defendants additionally argue that this omission was not material. Mot. at 14. The Court finds this argument more persuasive. Plaintiffs respond that omission of the CV side effects is material because "[e]vidence that Qsymia is associated with grave CV effects is an existential threat to Vivus[]," *see* Opp. at 15, but Mr. Tam's statement did not occur in a vacuum. Instead, it followed the February 2012 10-K, which disclosed the CHMP's concerns about CV risks, as well as the numerous disclosures regarding the potential for a required CV study, discussed above. Given this context, the Court finds that Plaintiffs have failed to allege "'a substantial likelihood that the disclosure of the [CV side effects on CNBC] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *See Matrixx*, 563 U.S. at 38. Instead, the reasonable investors would have already been aware of concerns about Qsiva's CV effects. Thus, the Court finds that Plaintiffs did not adequately plead materiality with respect to Mr. Tam's CNBC interview response.

In addition, the Court finds that Plaintiffs failed to allege scienter for this omission. As the Court explained in its First Dismissal Order, there are "no factual allegations to support a conclusion that Mr. Tam intended to mislead when he listed only some, but not all, of the possible side effects of Qsymia . . . given that Vivus otherwise fully disclosed those risks in its public filings." First Dismissal Order at 15. Plaintiffs have done nothing to cure this deficiency.

**3. Statements About Timing of Public Offering**

Finally, Plaintiffs' remaining allegations contend that Mr. Wilson knowingly misled investors who purchased Vivus stock on February 27, 2012 by stating on a TV appearance that day that Vivus planned to raise capital "at some time," when Vivus was already prepared to announce a public offering the very next day. SAC ¶¶ 11, 125. As Defendants note, the Court previously rejected nearly identical allegations in the FAC for failure to adequately plead falsity or materiality because "Plaintiffs' allegations do not support the conclusion that Defendants materially misled the public in stating that they would soon seek to raise capital when they, the day after making this statement, sought to raise capital." First Dismissal Order at 16.

Defendants argue that Plaintiffs have done nothing to cure this set of allegations. Instead, Plaintiffs continue to allege that Mr. Wilson made accurate statements—that Vivus would raise

funds for the FDA approval phase at most 6-7 weeks later. Mot. at 21. Defendants identify one new theory in the SAC—that Vivus misled the market by failing to disclose that it "was not in a favorable financial position to launch Qsymia," SAC ¶ 120—but argue that this, too, fails to plead falsity. Defendants explain that Vivus' financial position was a matter of public record set forth in the company's quarterly and annual SEC filings. Because Plaintiffs do not challenge the accuracy of those financial statements, nor Mr. Wilson's statement about Vivus' "$145 million in the bank," *id.* ¶ 124, Defendants contend that Vivus did not mislead investors about Vivus' financial position. Plaintiffs do not argue otherwise. *See* Opp. at 18-19.

The Court agrees that Plaintiffs have again failed to allege falsity regarding Mr. Wilson's description of Vivus' future stock offering. The offering was announced, but did not occur, the next day and it was used for commercialization, not approval, as Mr. Wilson stated. The Court also notes that Plaintiffs continued to purchase Vivus stock following the next day's public offering announcement, *see* SAC ¶ 86, casting doubt on the materiality of this alleged misrepresentation.

Furthermore, the Court finds that, even if Plaintiffs had sufficiently alleged that this statement constituted a material misrepresentation, Plaintiffs' allegations failed to give rise to a plausible inference of scienter. Plaintiffs contend that Defendants' individual stock sales, made the same day as Mr. Wilson's appearance on CNBC and right before Vivus' public offering announcement, are probative of scienter. Specifically, Plaintiffs allege that, on the day of the interview, Mr. Wilson sold 50,000 shares and another executive sold 47,078 shares. *Id.* ¶ 131. In addition, Plaintiffs allege that, over the prior week, Mr. Wilson and Mr. Morris exercised their options and sold 429,358 shares of Vivus stock. *Id*. The Court previously rejected this as a basis for scienter because Defendants showed that all of the stock sales referenced in the complaint were made pursuant to a Rule 10b5-1 trading plan. *See* First Dismissal Order at 18. Defendants make the same argument again, *see* Mot. at 23-24; *see also* RJN Exhs. 5-7, and the Court again agrees with Defendants.

Sales by securities defendants may be probative of scienter only if they are "'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from

undisclosed inside information.'" *Silicon Graphics*, 183 F.3d at 986 (quoting *In re Apple Computer Sec. Litig*., 886 F.2d 1109, 1117 (9th Cir. 1989)). In addition, "[s]ales according to pre-determined plans may rebut an inference of scienter." *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008) (internal citation omitted).

Here, Defendants offer the Individual Defendants' Form 4s (Statements of Changes in Beneficial Ownership) to show that each sale was made pursuant to the Individual Defendants' trading plan and, therefore, without the exercise of any discretion on their part. RJN Exh. 5-7, ECF 39-5 to 39-7. In addition, Plaintiffs allegations show that the February 27 sales did not represent the bulk of Individual Defendants' Vivus shares. *See* SAC ¶ 157 (describing sales following FDA approval).

Defendants additionally argue that the fact that these sales occurred on the day that Vivus announced the FDA panel's recommendation for approval of Qsymia is not suspicious. Mot. at 24. Though it is a profitable day to be sure, it also an obvious and appropriate opportunity to sell stock. *See Lipton v. Pathogenesis Corp*., 284 F.3d 1027, 1037 (9th Cir. 2002) ("Officers of publicly traded companies commonly make stock transactions following the public release of quarterly earnings and related financial disclosures."). On this basis, the Court finds that the Individual Defendants' stock sales on February 27, 2012 do not suffice to establish an inference of scienter with regard to Mr. Wilson's statements on CNBC.

Plaintiffs have failed to allege facts showing that Mr. Wilson said "at some time" instead of "tomorrow" to mislead investors. The opposing inference that Mr. Wilson was providing an accurate, if general, assessment of Vivus' fundraising plans is more compelling.

**B. Holistic Scienter Analysis**

Finally, the Court "consider[s] the complaint in its entirety" to determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs* at 322-23 (emphasis in original). "To determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 323-34. "[T]he inference of

scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling." *Id.* at 324.

To plead scienter in this case, Plaintiffs allege that Defendants had a strong motive to make false statements and that they knowingly made such statements. As discussed at length above, Plaintiffs allege that Defendants knew internally that the CHMP would not approve Qsiva unless Vivus conducted a CV study and addressed the Committee's other concerns first, but that they misrepresented these bars to approval in their public statements. SAC ¶ 154. With regard to motive, Plaintiffs allege that Defendants made these misrepresentations in order to artificially inflate the value of the Individual Defendants' Vivus shares and to maintain Vivus' position in the pharmaceuticals marketplace. *Id.* ¶¶ 155. As noted above, the bulk of Plaintiffs' scienter allegations focus on the stock sales Individual Defendants made around the time they also allegedly issued false and misleading statements. *Id.* ¶¶ 156-162.

Defendants argue that these allegations fail to raise a strong inference of deliberate wrongdoing because Plaintiffs have failed to sufficiently allege that Defendants made false or misleading statements, much less that they did so deliberately. Mot. at 22. Rather, they contend, Defendants did not know what the outcome of the EMA approval process would be until the agency reached its final decision, at which point Defendants disclosed it. *Id.* In addition, they argue that, if anything, a holistic approach reveals the thoroughness and detail of their risk disclosures, negating any inference of scienter. *Id.* at 23. Finally, as discussed above, Defendants argue that the 2012 stock sales cannot establish an inference of scienter because they were made according to Individual Defendants' pre-existing trading plans. *Id.* at 23-24.

The Court agrees with Defendants. Plaintiffs' allegations, taken together, do not give rise to a cogent inference of scienter. As discussed at length above, Plaintiffs may now be able to say, with the benefit of hindsight, that the CHMP required a CV study pre-approval and that its other concerns about side effects, stability, and the potential for off-label uses outweighed the benefits that the Committee saw in Qsiva. However, Plaintiffs have failed to allege facts to demonstrate that Defendants knew any of this at the time of their challenged statements.

Rather, Plaintiff's allegations combined with the judicially noticed CHMP reports show

that, following the 80 day mark, Defendants knew only that the rapporteurs took conflicting positions on which side effects could become serious impediments to approval. Though the CHMP offered more cohesive concerns in its 120 Day Report, Defendants knew that those concerns were "necessarily interim statements, subject to revision," *see Genzyme*, 2012 WL 1076124 at *10—knowledge that was confirmed by the opportunities the 180 Day Report presented to Defendants to convince the Committee that many of its concerns, from the need for a pre-approval CV study to the need for risk minimization plans for off-label use, were not justified.

Combining Plaintiffs' allegations regarding knowledge and falsity with their allegations about motive does nothing to save the scienter allegations. At most, the combination suggests motive and opportunity, but the Ninth Circuit requires more for a showing of scienter. *See Zucco*, 552 F.3d at 1005 ("If simple allegations of pecuniary motive were enough to establish scienter, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions") (internal citation omitted); *see also In re VeriFone Holdings*, 704 F.3d at 701 ("Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference.").

Here, Plaintiffs offer nothing beyond motive and opportunity. In fact, as noted above, any "reasonable inference of intent" that may arise from Defendants' positions, motivations, and stock sales are negated by the fluidity of the approval process and the divergent opinions of the committee members—which persisted even in the final vote. *See Genzyme*, 2012 WL 1076124 at *10. In addition, the Court agrees with Defendants that the thoroughness of their risk disclosures, which explicitly stated the significant cost, time, and risk that a CV study would involve and consistently cautioned that "[t]here can be no assurance that . . . our MAA will be approved by the CHMP," negate any inference of scienter even further.

Thus, taking the sum of Plaintiffs' allegations into account, the Court finds the inference that Defendants' statements about CHMP approval, the CV study, and other side effects reflected their optimism about the drug's launch—which ultimately flopped through mismanagement rather than fraud—far more compelling than an inference of fraudulent intent. Therefore, Plaintiffs have

failed to "state with particularity facts giving rise to a strong inference that . . . defendants engaged in knowing or intentional conduct." *See S. Ferry LP*, 542 F.3d at 782.

Because the Court must "compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive if the malicious inference is at least as compelling as any opposing innocent inference," *see Zucco*, 552 F.3d at 99, the SAC must be dismissed not only for failure to plead falsity and materiality, but also for failure to sufficiently plead scienter. Accordingly, the Court GRANTS Defendants' Motion to Dismiss the 10(b) and 10b-5 claims.

### C. Section 20(a) Claim

Section 20(a) provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controller person." A plaintiff suing under § 20(a) must demonstrate: (1) "a primary violation of federal securities laws" and (2) "that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000). Here, Plaintiffs' § 20(a) claims fail the first element. Because they have failed to state a claim for a primary violation of the Securities Act, they have also failed to state a § 20(a) claim. *See* First Dismissal Order at 20. Accordingly, the Court GRANTS Defendants' Motion to Dismiss the § 20(a) claims.

## IV. ORDER

At the hearing on this Motion, Plaintiffs stated that they could better explain the public record, but did not represent that they could offer new allegations. Accordingly, the Court GRANTS Defendants' Motion to Dismiss the Second Amended Complaint without leave to amend.

Dated: April 19, 2016

BETH LABSON FREEMAN
United States District Judge